

Food and Drug Administration, HHS

§ 890.5925

subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38818, July 25, 2001]

§ 890.5850 Powered muscle stimulator.

(a) *Identification.* A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

(b) *Classification.* Class II (performance standards).

§ 890.5860 Ultrasound and muscle stimulator.

(a) *Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions—(1) Identification.* An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. The device also passes electrical currents through the body area to stimulate or relax muscles.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasound and muscle stimulator for all other uses—(1) Identification.* An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section

is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5880 Multi-function physical therapy table.

(a) *Identification.* A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

(b) *Classification.* Class II (performance standards).

§ 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

(b) *Classification.* Class II (performance standards).

§ 890.5925 Traction accessory.

(a) *Identification.* A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current

§ 890.5940

good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5975 Therapeutic vibrator.

(a) *Identification.* A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

21 CFR Ch. I (4–1–14 Edition)

PART 892—RADIOLOGY DEVICES

Subpart A—General Provisions

Sec.

892.1 Scope.

892.3 Effective dates of requirement for pre-market approval.

892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

892.1000 Magnetic resonance diagnostic device.

892.1100 Scintillation (gamma) camera.

892.1110 Positron camera.

892.1130 Nuclear whole body counter.

892.1170 Bone densitometer.

892.1180 Bone sonometer.

892.1200 Emission computed tomography system.

892.1220 Fluorescent scanner.

892.1300 Nuclear rectilinear scanner.

892.1310 Nuclear tomography system.

892.1320 Nuclear uptake probe.

892.1330 Nuclear whole body scanner.

892.1350 Nuclear scanning bed.

892.1360 Radionuclide dose calibrator.

892.1370 Nuclear anthropomorphic phantom.

892.1380 Nuclear flood source phantom.

892.1390 Radionuclide rebreathing system.

892.1400 Nuclear sealed calibration source.

892.1410 Nuclear electrocardiograph synchronizer.

892.1420 Radionuclide test pattern phantom.

892.1540 Nonfetal ultrasonic monitor.

892.1550 Ultrasonic pulsed doppler imaging system.

892.1560 Ultrasonic pulsed echo imaging system.

892.1570 Diagnostic ultrasonic transducer.

892.1600 Angiographic x-ray system.

892.1610 Diagnostic x-ray beam-limiting device.

892.1620 Cine or spot fluorographic x-ray camera.

892.1630 Electrostatic x-ray imaging system.

892.1640 Radiographic film marking system.

892.1650 Image-intensified fluoroscopic x-ray system.

892.1660 Non-image-intensified fluoroscopic x-ray system.

892.1670 Spot-film device.

892.1680 Stationary x-ray system.

892.1700 Diagnostic x-ray high voltage generator.

892.1710 Mammographic x-ray system.

892.1715 Full-field digital mammography system.

892.1720 Mobile x-ray system.

892.1730 Photofluorographic x-ray system.

892.1740 Tomographic x-ray system.

892.1750 Computed tomography x-ray system.